REMARKS/ARGUMENTS

Rejection of Claims 41 and 42 under 35 U.S.C. §112, second paragraph.

The Examiner contends that the above-referenced claims are unclear in how the delivery of a lytic agent causes the intermittent mechanical motion of a catheter. The Examiner notes, however, that the specification discloses in the last paragraph of page 12 that the pulse wave forces of the pump as it delivers the lytic agent causes the intermittent mechanical motion of the catheter. In accord with the Examiner's tacit suggestion as to an appropriate claim amendment, Claim 41 has been appropriately amended and thus, Claims 41 and 42 are now believed to be in a condition for allowance.

Rejection of Claims 20-30 and 56 under 35 U.S.C. §102(e) as being anticipated by Monetti et al. '397

The Examiner rejects the above-referenced claims by contending that Monetti et al. disclose a pharmomechanical device comprising a catheter device comprising a catheter allegedly having a corkscrew configuration along its length, with the Examiner referring to Figure 2 of Monetti et al. The Examiner states that Monetti et al. discloses a catheter that rotates "between 30 rpm and 600 rpm", as allegedly disclosed in column 9, line 4. This is incorrect. Reference to such column and line number indicates that Monetti discloses that a drive shaft is rotated "on the order of about 500-3000 rpm in a single direction." The very title of Monetti et al. patent illustrates the difference between Monetti and the present invention: "Miniature Medical Brush". Indeed, Monetti et al. specifically disclosed that their miniaturized brush is formed at the distal end of an elongated brush drive shaft. There is no teaching whatsoever in Monetti et al. that a catheter is utilized that has a corkscrew configuration throughout its entire length and that such corkscrew catheter rotates at

speeds as low as 30 rpm. Indeed, Monetti et al. teaches away from the present invention by disclosing a more or less traditional and conventional miniaturized brush at the very end of a catheter, with a guide wire extending through a static lumen, such guide wire rotating in order to rotate the end bristles of a brush.

The above distinctions between the present invention and the features disclosed by Monetti et al. also apply to the dependent claims of independent Claim 20. With respect to Claim 27, Applicant has amended such claim to further clarify that the corkscrew catheter itself (not a spinning brush end) extends a substantial length of a blood vessel in which it is inserted. The Examiner contends that Claim 28 is rendered anticipated by Monetti et al. even though Monetti et al. never mention an occluding element. The fact that Monetti et al., discloses the release of a lytic agent through the drive shaft is not a teaching of a separate occluding element as described in the present specification. In any event, given that Claim 28 is dependent upon Claim 20, and the limitations of Claim 20 cannot be found or suggested by Monetti et al., Applicant respectfully requests that the Examiner to reconsider and withdraw all rejections based upon the Monetti et al reference.

Rejection of Claims 20-27, 29-30 and 56-58 under 35 U.S.C. §102(e) as being anticipated by Patterson et al. '329

The Examiner rejects the above-referenced claims on the basis that Patterson allegedly discloses a catheter having a corkscrew configuration as allegedly shown in Figure 5 and described in column 13, lines 37-39. The Examiner further contends that the catheter rotates between 30 rpm and 600 rpm as allegedly disclosed in column 17, line 18. Applicant respectfully traverses the Examiner's rejection of claims based upon Patterson for the following reasons.

First, Patterson is similar to Monetti et al. in that it discloses solely the use of a rotating "shearing body" that can be retracted within a sheath (i.e., the sheath/catheter does not rotate), as illustrated in Figure 5. Importantly, Patterson discloses that the shearing body in an exemplary embodiment comprises a helical row of radially aligned filaments, typically of a relatively short length (1.5 mm to 2 mm) (col. 7, lines 1-3). Patterson also discloses that the shearing body may be "brush-like" (col. 9, lines 27). Like conventional systems, Patterson teaches that a guide wire extends through a catheter and that it is the guide wire that is connected to the rotating brush. (See Col. 6, lines 33; etc.). Notably, Patterson's brush-like shearing bodies are designed to be "carried at the distal end of an inner catheter shaft." (Col. 10, lines 65-66). Patterson describes that the shearing body itself rotates, rather than the catheter. It is therefore undeniable that the corkscrew configuration existing throughout the length of the corkscrew catheter of the present invention is neither taught nor suggested by Patterson. Indeed, Patterson describes the use of well-known drive cables for use with this invention and describes the length of his catheter solely in terms of permitting the introduction of a brush to a target location. The catheter of Patterson is therefore clearly not intended to itself rotate and thereby breakup blood clots within a vessel. In this regard, Patterson can be seen as a teaching away, rather than towards, the present invention.

Also notably, the Examiner's reference to Figure 5 appears misplaced. Figure 5 is directed to a collapsed shearing body within a catheter such that the apparent corkscrew configuration is merely the compressed bristles of a brush-like shearing body within a catheter. In such position, the shearing body is admittedly retracted within a sheath and therefore cannot achieve any type of clot busting action. Although Patterson teaches that his shearing body can be rotated at rotational speeds

from 10 rpm to 10,000 rpm, the mere teaching of a slow speed rpm rotating brush at the end of a long catheter, which itself has no corkscrew configuration throughout its length, simply does not disclose, let alone teach or suggest, the present invention. Indeed, Patterson's teaching of the use of rpms of 6000 and up to 10,000 rpms is a further teaching away from the present invention which relies upon a much slower, corkscrew catheter rotation in order to achieve the desired mechanical motion of the catheter throughout its length.

The other dependent claims (e.g., Claims 21-23, 24-25 and 29-30), because they depend from independent claims, are clearly distinguishable from any teaching or disclosure of Patterson (along or with any other prior art).

Finally, with respect to Claims 57 and 58, the Examiner is incorrect when he characterizes Patterson as disclosing a catheter rotating at 30 rpm (allegedly finding support in Patterson, column 17, line 18). Indeed, Patterson simply discloses that the shearing body (not the catheter) is rotated at a wide range of speeds, preferably "from 60 rpm to 6000 rpm".

For all the foregoing reasons, Applicant respectfully requests the Examiner's reconsideration and favorable treatment of the claims based upon the arguments and claim amendments made herein. In the event the Examiner has any further questions or concerns with respect to the patentability of the present invention, Applicant's counsel requests the courtesy of a telephone interview and can be reached directly at 303-863-2977.

Applicant respectfully requests the Examiner's prompt attention to this matter as the original filing date of this case was nearly four years ago. Applicant has previously distinguished the present invention from the prior art of Cragg, Mische et al., Monetti et al. '397, Auth, and Patterson. The

present Examiner appears to be the third Examiner to have considered the claims as set forth in this case (with W. Lewis and Webb previously being the Examiners in the past). Applicant's counsel would therefore truly appreciate the Examiner's indulgence in addressing any existing concerns hereinafter in a prompt telephone interview so that appropriate claim amendments can, if at all deemed necessary, be promptly addressed and considered.

Respectfully submitted,

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